February 16, 2000

MEMORANDUM

SUBJECT: Response to Public Comments on the Preliminary Risk Assessments for the Organophosphate **Methamidophos**

FROM: Kimberly Lowe, Chemical Review Manager
Special Review and Reregistration Division
Office of Pesticide Programs

TO: OPP Public Docket for Methamidophos

Introduction

This document addresses public comments received in response to EPA's Notice of Availability (64 FR 1199, January 8, 1999) of preliminary risk assessment[s] for five organophosphate chemicals, which included methamidophos, along with four other active ingredients. Part I of this document addresses comments received specific to methamidophos, and Part II discusses whether any non-chemical-specific comments were received. By "non-chemical-specific" we mean that the comment was submitted to the OPP Public Dockets for each of organophosphate chemicals. Also, these non-chemical-specific comments generally apply to regulatory or science policy issues that are not unique to any one of the chemicals or risk assessments.

Part I. Methamidophos-Specific Comments and Responses

Methamidophos-specific comments were received from Bayer Corporation (Bayer), the California Department of Pesticide Regulation (CDPR), the National Potato Council (NPC), and the Washington State Department of Agriculture (WSDA). Full responses to comments are outlined in an August 8, 1999, memorandum from Felecia Fort to Kimberly Lowe and a September 15, 1999, memorandum from Stephanie Syslo and Michael Davy to Kimberly Lowe. Both memoranda are contained in this docket.

A. Response to Comments on Preliminary Human Health Risk Assessment

1. Comments from Bayer Corporation

Comment #1: Bayer, the registrant, disagrees with the Agency's decision not to use a subchronic oral human toxicity study in establishing Acute and Chronic endpoints for the risk assessment. Also, based on the availability of the human study, Bayer proposed that the 10x uncertainty factor for interspecies extrapolation be removed.

> **Response:** Regarding Bayer's comments on the use of human data in the methamidophos risk assessment, an Agency policy regarding the use of human data has not yet been finalized. In addition, EPA has determined that the human subchronic study in reference is unacceptable.

Comment #2: Bayer also submitted comments related to the occupational section of the revised risk assessment; specifically, Bayer states that the long and safe use history of methamidophos should be considered, and that Bayer has worked with EPA over the last 10 years to reduce the potential for worker exposure associated with methamidophos.

> **Response:** EPA acknowledges Bayer's product stewardship in reducing the potential for worker exposure to methamidophos, and appreciates Bayer's efforts.

Other Submissions: The registrant also submitted new data and analyses to refine the dietary and occupational exposure assessments. For the dietary assessment, Bayer submitted a Tier 3 Monte Carlo (probabilistic) analysis for acute dietary exposure to methamidophos and a Tier 3 analysis for chronic exposure to methamidophos. Additional studies submitted by the registrant include a 21-Day dermal toxicity study, two studies supplementing a two-generation dietary reproduction study in rats, and magnitude of the residue studies. For the worker assessment, Bayer referred to dislodgeable foliar residue studies on potatoes and tomatoes submitted in October 1998 in response to the Agricultural Reentry Data Call-In.

> **Response:** All studies and risk analyses submitted during and after the comment period are incorporated into the revised human health risk assessment for methamidophos. HED has reviewed the probabilistic assessment, and the results of that review are presented in the dietary exposure assessment memorandum available in this docket (October 4, 1999, memorandum from Felecia Fort and Kristina El-Attar to Kimberly Lowe). The revised risk assessment contains further detail on how each of the studies are used in the Agency's risk analysis.

2. Comments from the California Department of Pesticide Regulation

Comment #1: CDPR is working on a risk characterization document on methamidophos, and submitted several comments on EPA's risk assessment, including results from CDPRs reviews of the same studies being used and/or considered by EPA and LOEL and NOEL values that CDPR used in its risk characterization document.

> **Response:** EPA appreciates CDPR's comments, and looked at the results of CDPR's reviews and CDPR's LOEL and NOEL values. EPA has requested a copy of CDPR's risk assessment.

Comment #2: CDPR also questioned whether degradates are being considered for inclusion in the tolerance expression, and stated that recent literature reports suggest that degradates or metabolites of methamidophos may contribute to the overall toxicity.

> **Response:** EPA looks at metabolism studies conducted using a minimum of three diverse crops and determines the residues to be regulated. Based on metabolism studies conducted on beans, cotton, and lettuce, and significantly lower concentrations of metabolites, EPA has determined that the residue to be regulated is methamidophos. If evidence becomes available supporting the inclusion of additional residues of concern, EPA will reassess the situation.

3. Comments from the National Potato Council

Comment #1: The National Potato Council provided extensive comments regarding the human health risk assessment, including a scientific critique that argues that EPA's risk estimation is exaggerated for three reasons: the chronic RfD is unreasonably conservative because EPA failed to acknowledge the value of a human study, the application of the 3x safety factor is unreasonable, and the EPA has overlooked recent information concerning antagonistic interactions of acephate and methamidophos.

> **Response:**
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> EPA does not feel that its risk estimation is exaggerated. As stated above in response to Bayer's comments, EPA is following the Scientific Advisory Panel's recommendation not to use human data at this time. In addition, EPA has determined that the human subchronic study in reference is unacceptable.
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> EPA disagrees that the application of the 3x FQPA safety factor, is unreasonable. EPA believes that the available data provide qualitative evidence of the inherent neurotoxicity of methamidophos, and the 3x FQPA safety factor will be retained.

In aggregating risk from methamidophos, EPA is not considering simultaneous exposure to acephate and methamidophos, but rather the residues that are representative of actual methamidophos residues that may be found as a result of application of methamidophos or acephate. The anticipated residues of methamidophos from the application of acephate are representative of actual methamidophos residues found when acephate was applied. Mechanistic data concerning the antagonistic interactions of pesticides will be addressed when a cumulative assessment is conducted for all organophosphate pesticides.

Comment #2: NPC also provided information concerning the benefits of methamidophos and expressed concern regarding competitive fairness issues between US potato growers and potato growers from outside of the US.

Response: EPA thanks the NPC for the information provided and appreciates that there is significant concern among potato growers with regards to this chemical. With regards to the benefits information, this will be considered and used where appropriate in the Agency's decision-making process. Regarding the competitive fairness issue, the United States does not have authority over the use practices in other countries; however, we acknowledge potato growers' concerns and will discuss this issue further if the need arises.

B. Response to Comments on the Preliminary Ecological Risk Assessment

1. Comments from Bayer Corporation

Comment #1: Bayer provided extensive comments on the water assessment, specifically surface water exposure modeling. Bayer believes that the Tier II assessment contained critical errors.

Response: EPA has considered Bayer's comments and made changes to the surface water exposure model inputs as necessary. Text in the risk assessment and tables were corrected to reflect these changes; however, the qualitative conclusions of the risk assessment do not change.

Comment #2: Bayer also stated that water monitoring data will be available for methamidophos from the NAWQA program shortly.

Response: EPA notes that water monitoring data will become available from NAWQA monitoring, and acknowledges that this information will be helpful for the human health assessment. EPA also recommends that residues be measured in both the "raw" and "finished" water. NAWQA data may be helpful for assessing ecological risk if samples are taken at times of peak use of methamidophos.

Comment #3: Bayer provided rebuttal summaries to the reviews of several environmental fate studies.

> **Response:** Responses to each of Bayer's rebuttal comments are detailed in the September 15, 1999, memorandum referenced above. In cases where the Agency accepts Bayer's lines of reasoning, the studies have been used to fulfill data requirements.

2. Comments from Washington State Department of Agriculture

Comment: A Pesticide Registration Specialist from the WSDA commented that Washington State University Research indicates that 1) methamidophos residues are hazardous to honeybees for one day after application, 2) methamidophos residues can be hazardous to other bee species for up to 5 days after application, and 3) methamidophos drift onto vegetable or legume seed crops can cause a serious problem for bees. WSDA is recommending that EPA require methamidophos labels to warn applicators of the hazards of drift.

> **Response:** EPA is aware of the toxicity to bees and will consider a variety of options to address this issue, including a label warning. Its decision will be presented in the Reregistration Eligibility Decision for this chemical.

3. Comments from the National Potato Council

Comment #1: The NPC questioned the Agency's use of modeling to provide estimates of residues on crops to determine ecological risk rather than field data from a potato field.

> **Response:** EPA uses the model results in this instance because the model is considered to be a better estimate of residues on crops than the referenced study conducted on one field and one crop. The model is based on several hundred residue endpoints from many different fields and crops and was later independently verified. Further information on the model is provided in the attached September 15, 1999, memorandum (referenced above). However, EPA will consider any technically valid and statistically robust studies of residues on avian food items.

Comment #2: The NPC also questioned the validity of reports of avian mortality from the 1980s. NPC also mentioned that no incidents had occurred in the 1990s and concluded that incidents are infrequent and that risk quotients do not reflect actual use experience.

> **Response:** EPA has confidence in the reported incidents because investigation reports are submitted to EPA under FIFRA 6(a)(2). It is also important to mention that mortality incidents are often not seen due to scavenger removal of carcasses, decay, and/or simply because people are not systematically looking for them. Also, poisoned animals may move to less conspicuous areas before dying. For these and many other reasons listed in the

attached September 15, 1999, memorandum, EPA believes that the reported incidents reflect only a fraction of the total mortality caused by highly toxic pesticides.

Part II: Non-Chemical-Specific Comments and Responses

There were no non-chemical-specific comments received in response to this public docket. Some of the chemical-specific comments received relate to Agency policy, and were addressed, as appropriate, in Part I of this document.